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9	4	("4903695" "4994058" "5196027" "5336215").PN.	USPAT	2004/01/25 16:36
10	12	5549632.URPN.	USPAT	2004/01/25 16:39
11	24	((606/4-6,10,13,166).CCLS.) and (attachment same ring)) and (flexible same ring\$1)	USPAT; US-PPGPUB; EPO; JPO; DERWENT; IBM TDB	2004/01/25 17:07
-	107	'aplanatic lens'	USPAT; US-PPGPUB; EPO; JPO; DERWENT; IBM TDB	2003/01/25 19:03
-	1	'applanation lens'	USPAT; US-PPGPUB; EPO; JPO; DERWENT; IBM TDB	2003/01/26 12:19
-	135	'flattening lens'	USPAT; US-PPGPUB; EPO; JPO; DERWENT; IBM TDB	2002/07/26 14:35
-	568	(606/4-6).CCLS.	USPAT	2003/01/26 12:12
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-	1	('aplanatic lens') and ((606/4-6).CCLS.)	USPAT	2002/07/26 13:42
-	15	("4665913" "4669466" "4712543" "4718418" "4729372" "4732148" "4772115" "4856513" "4905711" "4907872" "5108412" "5336215" "5549632" "5817115" "6126668").PN.	USPAT	2002/07/26 13:41
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-	2	('aplanatic lens') and (fused adj silica)	USPAT	2002/07/26 14:34
-	0	('aplanatic lens') and ('SiO2')	USPAT	2002/07/26 14:35

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	16	(Kyle near2 Webb).in.	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2002/07/26 14:55
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-	1	("5549632").PN.	USPAT	2003/01/26 13:04
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	<input checked="" type="checkbox"/> 1	Document ID	Title	Current OR
1	<input checked="" type="checkbox"/>	US 6447449 B1	System for measuring intraocular pressure of an eye and a MEM sensor for use therewith	600/405
2	<input checked="" type="checkbox"/>	US 2002010348 2 A1	Applanation lens and method for ophthalmic surgical applications	606/5
3	<input checked="" type="checkbox"/>	US 5549632 A	Method and apparatus for ophthalmic	606/5
4	<input checked="" type="checkbox"/>	US 6325792 B1	Ophthalmic surgical laser and method	606/4
5	<input checked="" type="checkbox"/>	US 5540227 A	Controlled application of select ophthalmic agents	600/405
6	<input checked="" type="checkbox"/>	US 6254595 B1	Corneal aplanation device	606/5
7	<input checked="" type="checkbox"/>	US 6126668 A	Microkeratome	606/166
8	<input checked="" type="checkbox"/>	US 5336215 A	Eye stabilizing mechanism for use in ophthalmic laser surgery	606/4
9	<input checked="" type="checkbox"/>	US 4907872 A	Contact lens for enabling treatment of the eye by laser	351/160R
10	<input checked="" type="checkbox"/>	US 5108412 A	Suction ring for surgical operations on the human eye	606/166
11	<input checked="" type="checkbox"/>	US 4905711 A	Eye restraining device	128/869
12	<input checked="" type="checkbox"/>	US 4856513 A	Laser reprofiling systems and methods	606/5
13	<input checked="" type="checkbox"/>	US 4732148 A	Method for performing ophthalmic laser surgery	606/5

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6	Juhasz, Tibor et al.
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8	Hsueh, Chi-Fu et al.
9	Schirmer, K. E. et al.
10	Krumeich, Jorg H. et al.
11	Bennett, Peter S. et al.
12	Muller, David F.
13	L'Esperance, Jr., Francis A.

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14	<input checked="" type="checkbox"/>	US 4729372 A	Apparatus for performing ophthalmic laser surgery	606/5
15	<input checked="" type="checkbox"/>	US 4712543 A	Process for recurving the cornea of an eye	606/5
16	<input checked="" type="checkbox"/>	US 4718418 A	Apparatus for ophthalmological surgery	606/5
17	<input checked="" type="checkbox"/>	US 4669466 A	Method and apparatus for analysis and correction of abnormal refractive errors of the eye	606/3
18	<input checked="" type="checkbox"/>	US 4665913 A	Method for ophthalmological surgery	606/3
19	<input checked="" type="checkbox"/>	US 6118474 A	Omnidirectional imaging apparatus	348/36
20	<input checked="" type="checkbox"/>	US 5282088 A	Aplanatic microlens and method for making same	359/664
21	<input checked="" type="checkbox"/>	US 20010021844 A1	Device and method for reducing corneal induced aberrations during ophthalmic laser surgery	606/5
22	<input checked="" type="checkbox"/>	US D459807 S	Patient interface gripper for ophthalmic laser	D24/150

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20	Davidson, Mark
21	Kurtz, Ronald M. et al.
22	Webb, R. Kyle

	<input checked="" type="checkbox"/> 1	Document ID	Title	Current OR
23	<input checked="" type="checkbox"/>	US D462443 S	Applanation lens cone for ophthalmic laser surgery	D24/150
24	<input checked="" type="checkbox"/>	US 2002010348 1 A1	Ocular fixation and stabilization device for ophthalmic surgical applications	606/5
25	<input checked="" type="checkbox"/>	US 2002010348 2 A	Applanation lens for ophthalmic laser surgery has applanation surface that contacts and flattens anterior surface of eye upon application of pressure	
26	<input checked="" type="checkbox"/>	US 6676653 B2	Device and method for removing gas and debris during the photodisruption of stromal tissue	606/4
27	<input checked="" type="checkbox"/>	US 6623476 B2	Device and method for reducing corneal induced aberrations during ophthalmic laser surgery	606/5
28	<input checked="" type="checkbox"/>	US 6373571 B1	Disposable contact lens for use with an ophthalmic laser system	356/399
29	<input checked="" type="checkbox"/>	US 5196027 A	Apparatus and process for application and adjustable reprofiling of synthetic lenticules for vision correction	128/898

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23	Webb, R. Kyle
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25	SCHOLLER, G S et al.
26	Juhasz, Tibor et al.
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	<u>1</u>	Document ID	Title	Current OR
30	<input checked="" type="checkbox"/>	US 4994058 A	Surface shaping using lasers	606/5

Inventor	
30	Raven, Antony L. et al.

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Document Listing

Document	Image pages	Text pages	Error pages
US 5336215 A	7	0	0
Total	7	0	0



US005336215A

United States Patent [19]

Hsueh et al.

[11] Patent Number: 5,336,215

[45] Date of Patent: Aug. 9, 1994

[54] EYE STABILIZING MECHANISM FOR USE IN OPHTHALMIC LASER SURGERY

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5,226,903 7/1993 Mizuno 606/4 X

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[21] Appl. No.: 8,010

[22] Filed: Jan. 22, 1993

[51] Int. Cl.⁵ A61N 5/06

[52] U.S. Cl. 606/4; 606/5;
606/6; 606/17; 606/10

[58] **Field of Search** 606/4, 5, 6, 107, 17,
606/10

[56] References Cited

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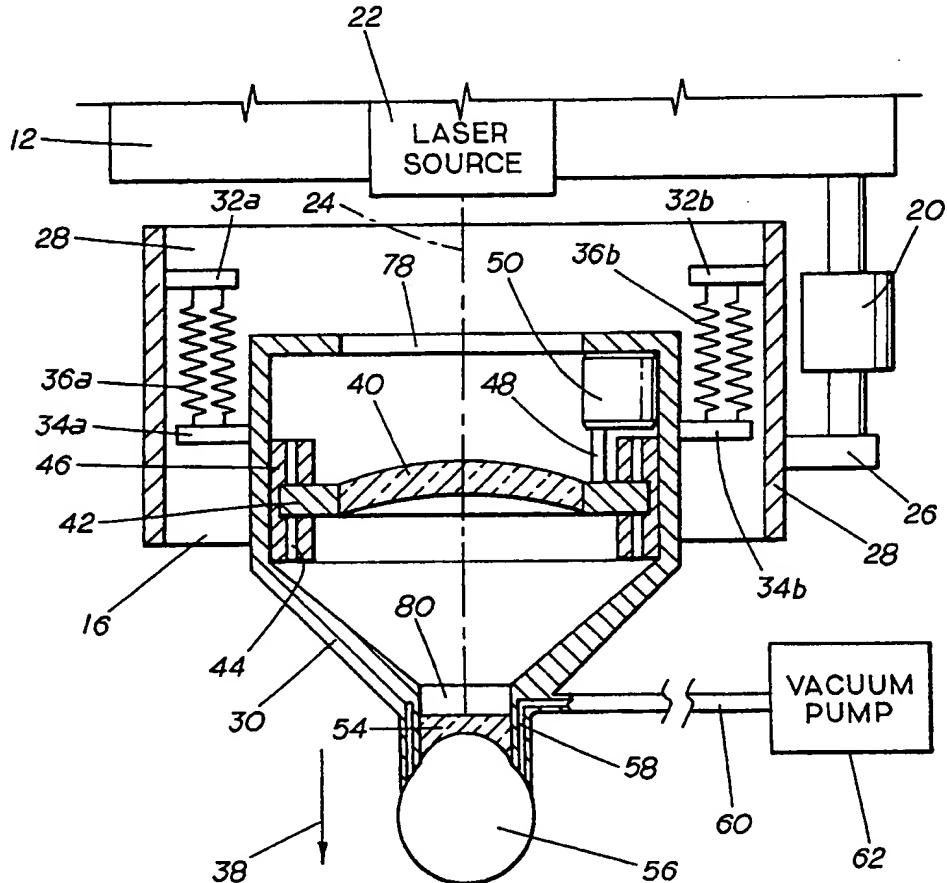
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*Primary Examiner—Peter A. Aschenbrenner
Attorney, Agent, or Firm—Nydegger & Associates*

[57] **ABSTRACT**

An eye stabilizing mechanism for use with a computer controlled ophthalmic laser system includes a base on which the ophthalmic laser system is mounted. A frame is slidingly mounted on the base, and the frame is connected to the base by a linear spring. A contact lens is fixedly attached to the frame and an object lens is slidingly mounted on the frame. An object lens activating device is also fixedly attached to the frame, and this device is connected to the object lens to move the object lens in accordance with preprogrammed instructions from the computer. Thus, while contact is maintained between the surface of the eye and the contact lens, the object lens can be moved by computer control to move the focal point of the laser system through selected eye tissue. Also, any movement of the frame, due to movement of the eye, is opposed only by the substantially constant force which is established by the linear spring between the base and the frame.

21 Claims, 1 Drawing Sheet



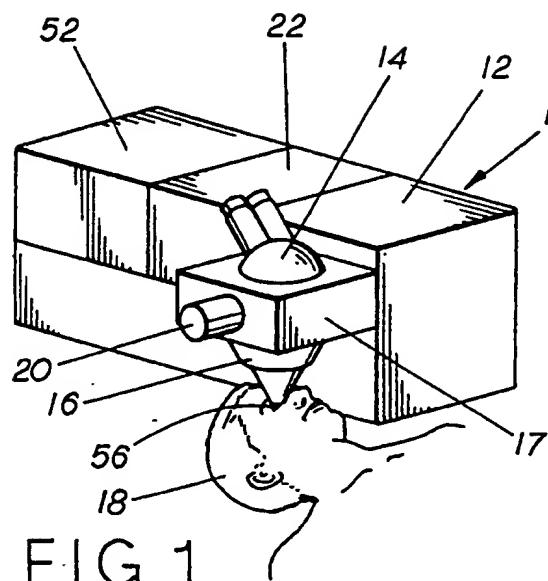


FIG. 1

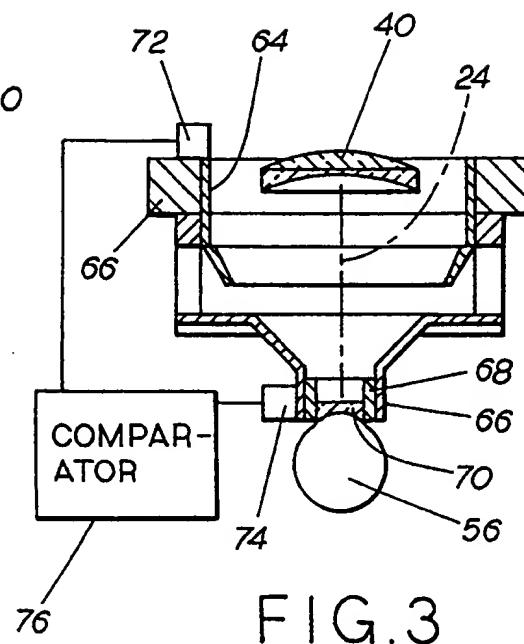


FIG. 3

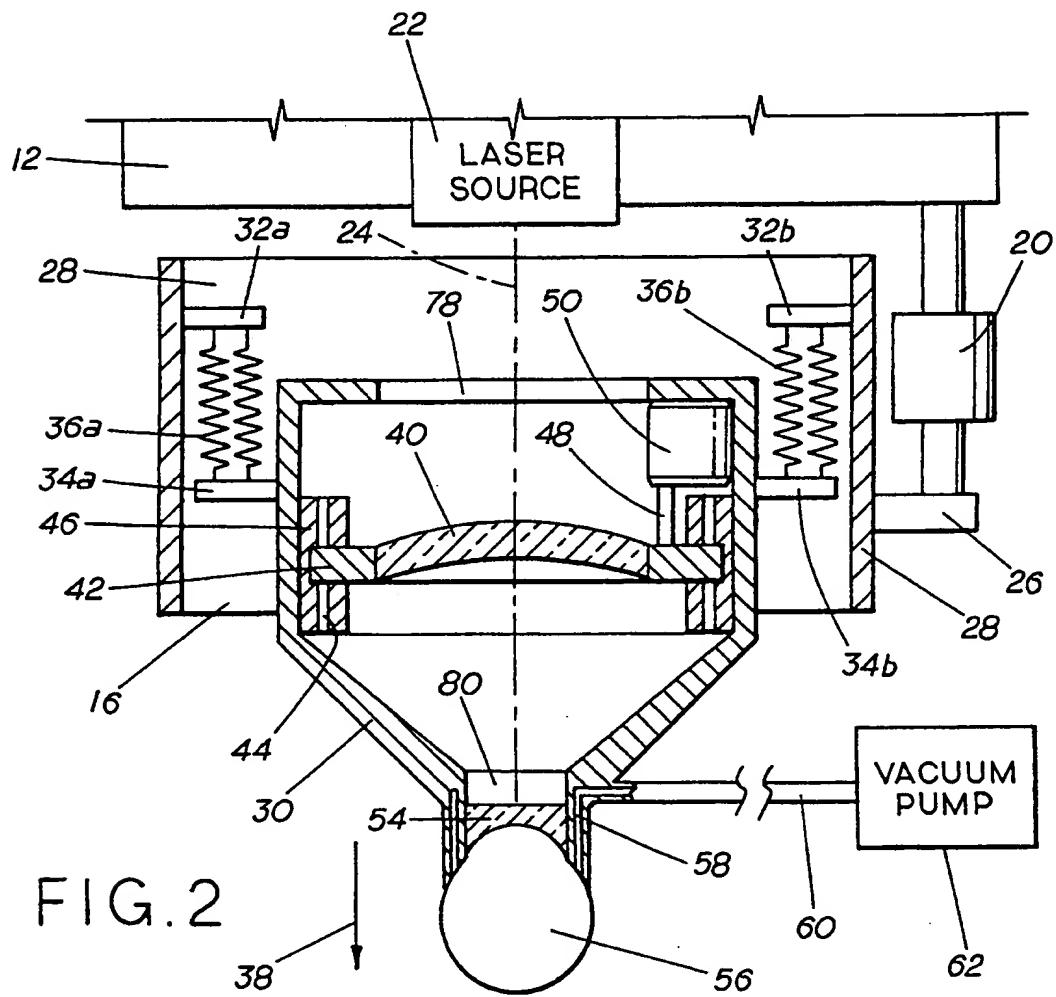


FIG. 2

EYE STABILIZING MECHANISM FOR USE IN OPHTHALMIC LASER SURGERY

FIELD OF THE INVENTION

The present invention pertains to devices which are useful for ophthalmic surgery. More particularly, the present invention is useful for stabilizing the eye of a patient during ophthalmic surgery wherein a laser system is used to alter selected tissue of the eye. The present invention is particularly, but not exclusively, useful for maintaining the eye of a patient in a predetermined position relative to the focal point of a laser beam, by physically constraining eye movement during ophthalmic laser surgery.

BACKGROUND OF THE INVENTION

Ophthalmic surgery is, unquestionably, one of the more complicated and difficult areas of medical practice. Though ophthalmic surgery is not normally a life threatening procedure, there is always the possibility of irreversible complications. Thus, ophthalmic surgery must be accomplished with great care and extreme precision.

In recent years, developments in laser systems have made new applications and new surgical procedures possible. One consequence of this is that ophthalmic surgery can be accomplished with greater surgical precision. Despite the advances in laser technology, the use of lasers for ophthalmic surgery still has certain operational limitations. Most importantly, it is absolutely essential that the laser be properly controlled during a surgical procedure. This requires that the proper position of the eye relative to the focal point of the laser be maintained at all times during the surgical procedure. Stated differently, the eye must remain stabilized in its relation to the laser system.

Although laser surgery can be accomplished relatively quickly, it still requires time. As a practical matter, movement of the laser's focal point must be accomplished with such extreme precision during a surgical operation that even the slightest movement of the eye can not be tolerated. Unfortunately, it is physically impossible for a patient to hold his/her eye sufficiently still for the length of time required to accomplish a surgical laser operation. Consequently, the eye must somehow be stabilized.

Essentially, there are two ways by which a patient's eye can be stabilized or held still relative to a laser system during an ophthalmic laser operation. One requires an optical link between the eye and the laser system, while the other requires a mechanical link. For an optical link, an optical arrangement which uses light reflections from the eye to generate signals that indicate eye movement is incorporated into the laser system. The laser system then uses these signals to compensate for eye movement. U.S. Pat. No. 4,848,340 which issued to Bille et al. for an invention entitled "Eyetracker and Method of Use", and which is assigned to the same assignee as the present invention, discloses such an optical arrangement. The second way is to mechanically stabilize the eye in its spacial relationship with the laser system through direct contact of the laser system's optical componentry with the eye. U.S. Pat. No. 4,712,543 which issued to Baron for an invention entitled "Process for Recurving the Cornea of an Eye" discloses such a system.

Regardless whether the eye stabilizing mechanism is an optical arrangement or a mechanical system, the mechanism must be compatible with the capabilities of the ophthalmic laser system with which it is used. In particular, the eye stabilizing mechanism must not limit the capabilities of the ophthalmic laser system. As can be easily appreciated, compatibility issues are even more pronounced when the laser system, as here, is computer controlled.

In light of the above, it is an object of the present invention to provide a mechanism which is useful for stabilizing an eye with a contact lens during ophthalmic laser surgery. It is another object of the present invention to provide an eye stabilizing mechanism which is incorporated directly into the optical system of a surgical laser generating device. Still another object of the present invention is to provide an eye stabilizing mechanism which establishes reliable contact between the laser system and the eye during ophthalmic laser surgery. Yet another object of the present invention is to provide an eye stabilizing mechanism which is operatively compatible with a computer controlled laser system. Another object of the present invention is to provide an eye stabilizing mechanism which does not cause injury or discomfort to the eye during surgery. It is also an object of the present invention to provide an eye stabilizing mechanism which is easy to use, relatively easy to manufacture and which is comparatively cost effective.

SUMMARY OF THE INVENTION

In accordance with the present invention, a device is disclosed which is useful with a laser system to mechanically stabilize the eye of a patient during ophthalmic laser surgery. The major components of this device include a base member, a frame member which is slidably suspended on the base member, and a movable objective lens which is slidably mounted on the frame. Additionally, there is a contact lens that is fixedly mounted on the frame. This contact lens is contoured to conform to the surface of the eye for stabilizing engagement with the eye during surgery.

A compensating device, such as a linear force spring, connects the frame to the base member. Consequently, any sliding movement of the frame, and the objective lens along the base is opposed by the substantially constant force that is created by the spring. With this system, as the contact lens is initially positioned against the surface of the eye, a compensator force dependent on the substantially constant spring force is established between the contact lens and the eye. Thereafter, the force that is equivalent to the substantially constant spring force is maintained between the eye and the contact lens during any subsequent movement of the eye relative to the base.

As intended for the eye stabilizing mechanism of the present invention, a computer controlled laser system is provided which directs its laser beam through both the object lens and the contact lens. However, in order to control movement of the laser beam's focal point through selected eye tissue, the objective lens must be moveable relative to the contact lens. Consequently, an objective lens activating device, such as a galvo or a voice coil, is mounted directly on the frame and is connected to the objective lens to move the objective lens in accordance with preprogrammed instructions from the computer.

In addition to the substantially constant force which the mechanism of the present invention maintains between the surface of the eye and the contact lens, it can also include suction means for holding the contact lens against the surface of the eye. This additional feature can be established by forming channels in the frame which have openings near the periphery of the contact lens. A vacuum pump can then be connected in fluid communication with the channels via a flexible tube to establish a suction effect against the surface of the eye at 10 the peripheral channel openings. When the eye's surface is in contact with the contact lens, this suction helps hold the eye against the contact lens.

In an alternate embodiment of the present invention, the frame can be fixedly mounted to the base with the contact lens slidably mounted on the frame. The stabilizing force between the contact lens and the surface of the eye can then be established by the weight of the contact lens and its support structure. For the alternate embodiment of the present invention, the mechanism also includes a first sensing means for locating the position of the contact lens relative to the frame, and a second sensing means for locating the position of the object lens relative to the frame. Again, the laser system is computer controlled. For the alternate embodiment, however, the computer uses signal from both the first and second sensing means to control movement of the object lens. Specifically, the movement of the object lens is controlled relative to the location of the contact lens for moving the laser system's focal point through 30 eye tissue in accordance with preprogrammed instructions.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of this invention, as well as the invention itself, both as to its structure and its operation will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

FIG. 1 is a perspective view of an ophthalmic surgical laser system which incorporates the eye stabilizing mechanism of the present invention, with the eyestabilizing mechanism in engagement with the eye of a patient;

FIG. 2 is an elevational schematic drawing of the eye stabilizing mechanism of the present invention and its connections to the laser system, with portions shown in cross section for clarity; and

FIG. 3 is an elevational schematic drawing of an alternate embodiment of the eye stabilizing mechanism of the present invention with portions shown in cross section for clarity.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring initially to FIG. 1, an ophthalmic laser system is shown and generally designated 10. For purposes of the present invention, the ophthalmic laser system 10 can be of any type well known in the pertinent art which uses a focused beam of laser energy to surgically alter the tissue of any eye. As shown, the laser system 10 includes a housing 12 on which a microscope 14 is mounted. The laser system 10 also includes an eye stabilizing mechanism, generally designated 16, which is mounted on a moveable platform 17 of the housing 12 for movement into contact with the eye of a patient 18 by operation of a motor 20.

Referring now to FIG. 2 it will be seen that a laser source 22 is mounted on the housing 12 of laser system 10. The laser source 22 can be of any type well known in the art which is capable of generating an ophthalmic laser beam 24. Furthermore, although the specific optical arrangement used to direct the laser beam 24 from laser source 22 to patient 18 through system 10 is not shown, it is to be appreciated that any known optical arrangement can be employed. The main concern is that the optical arrangement satisfy the needs of the operator and be compatible for use with the laser source 22 and the generated laser beam 24.

FIG. 2 shows that laser system 10 relies on a stable structural connection between the laser source 22 and eye stabilizing mechanism 16. For this purpose, it is shown that the laser source 22 is directly mounted on housing 12, and that the housing 12 includes a connector 26 which is fixedly attached to the base 28 of mechanism 16. As indicated above, however, it is necessary to be able to move and position the mechanism 16 in contact with the eye of patient 18 at the beginning of a surgical procedure. To do this, the activating motor 20 is provided between housing 12 and connector 26 which is part of platform 17 (not shown in FIG. 2). Motor 20 can be of any type which is well known in the pertinent art. And, although motor 20 can be activated to change the position of the entire mechanism 16 relative to housing 12, once an adjustment has been made with motor 20, the relationship between housing 12 and base 28 of mechanism 16 is fixed.

Still referring to FIG. 2 it is to be seen that eye stabilizing mechanism 16 includes a frame 30 which is suspended from the base 28. More specifically, an upper arm 32a,b is fixedly attached to the base 28 and a lower arm 34a,b is fixedly attached to the frame 30. A compensating device, such as a linear force spring 36a,b, interconnects the respective upper arm 32a,b to the lower arm 34a,b. Preferably, this compensating mechanism is a spring device, such as a constant force spring which generates a substantially constant force in opposition to any movement of the frame 30 relative to base 28 in the directions indicated by arrow 38. Through this compensating device, the frame 30 is suspended from base 28 and importantly, due to the linear force generated by springs 36a,b, any displacement of frame 30 from its equilibrium position will create a substantially constant opposing force. Preferably, this opposing force is in the approximate range of from zero to three hundred grams (0-300 gms). It is to be appreciated that means known in the art can be used to establish a desired value for this force according to the needs of the operator. In accordance with the present invention, a plurality of compensating mechanisms 36 can be employed.

An objective lens 40 is slidably mounted on the frame 30. More specifically, the lens 40 is held in a bracket 42 which has projections (not shown) that engage with the tracks 44 of a slide 46 that is mounted on the base 28. It is to be understood that there may be a plurality of slides 46, and that each slide 46 includes a pair of opposed tracks 44 which engage with the projections of a respective bracket 42 to allow a sliding movement of the frame 30 relative to the base 28. It is, of course, within the scope of the present invention to use any other type mechanism which is well known in the pertinent art and which allows the frame 30 to freely slide relative to the base 28.

The ophthalmic laser system 10 of the present invention also includes a link 48 which mechanically connects the objective lens 40 to an objective lens actuator 50. Importantly, the actuator 50 is mounted directly on the frame 30 for movement with the frame 30. Preferably, the objective lens actuator 50 is a GALVO, of a type well known in the pertinent art, but it can also be any other type actuator which is capable of sliding the objective lens along the frame 30 in a manner required for operation of the system 10, such as a voice coil.

Both the actuator 50 and the laser source 22 are electronically connected to a computer 52 which may be mounted in the housing 12 of laser system 10. With these electronic connections (not shown), actuator 50 is activated to move objective lens 40 back and forth on frame 30 in accordance with preprogrammed instructions from the computer 52 for the purpose of moving the focal point of laser beam 24 along a prescribed path for completion of the desired ophthalmic surgery.

FIG. 2 also shows that a contact lens 54 is mounted on frame 30 along the path of laser beam 24. This contact lens 54 is contoured to conform to the outer surface of the cornea of an eye 56 of the patient 18 and is made of any suitable material which is clear and which has minimal light dispersive properties. Additionally, it is shown that the frame 30 is formed with at least one channel 58 which has an open end near the periphery of the contact lens 54. A flexible tube 60 is provided which connects the channel 58, or all of the channels 58 if more than one channel 58 is used, with a vacuum pump 62. Consequently, upon engagement of the contact lens 54 with the cornea of eye 56, vacuum pump 62 can be operated to create a partial vacuum in the channel 58 which will assist in holding the eye 56 against the contact lens 54.

In an alternate embodiment of the present invention for an eye stabilizing mechanism, as shown in FIG. 3, an objective lens 40 is fixedly mounted on a bracket 64. The bracket 64, however, is slidably supported on a frame 66. Further, this embodiment of the present invention includes a support 68 which is also slidably supported on the frame 66. A contact lens 70 is then fixedly mounted on the support 68 for movement therewith relative to the frame 66. As for the preferred embodiment of the present invention, the contact lens 70 is contoured to conform to the outer surface of the cornea of the eye 56 of a patient 18. In accordance with the alternate embodiment of the present invention, however, the force which is generated to maintain contact between the eye 56 and the contact lens 70 is provided by the weight of the contact lens 70 and its support 68. Other mechanisms, of course, can be used. The important thing is that a substantially constant force be generated between the contact lens 70 and the eye 56. Again, this force is preferably in the approximate range of from ten to forty grams (10-40 gms).

Though not shown in FIG. 3, it is to be appreciated that a GALVO or some other appropriate activating mechanism, such as described above for the preferred embodiment, is used to move the bracket 64 and objective lens 40 relative to the frame 66. As shown in FIG. 3, the alternate embodiment of the present invention includes a sensor 72 which is mounted on frame 66 for the purpose of sensing movement between the objective lens 40 on bracket 64 and the frame 66. Similarly, a sensor 74 is mounted on frame 66 for the purpose of sensing movement between the contact lens 70 on support 68 and the frame 66.

A comparator 76 is electronically connected to both of the sensors 72 and 74 and, in accordance with preprogrammed instructions, the computer 76 uses signals from the sensors 72 and 74 to maintain the proper distance between objective lens 40 and contact lens 70 during an ophthalmic surgical operation. Though no actual electronic connections are shown, it is to be appreciated that the comparator 76 is part of the electronic system which is schematically shown in FIG. 1 and designated 52.

Operation

In the operation of the present invention, a patient 18 is positioned relative to the laser system 10 so that the operator can engage contact lens 54 with the eye 56 of patient 18. To do this, the operator, while viewing the patient's eye 56 through the eyepiece 14, manipulates the adjustment knob 20 to bring contact lens 54 of mechanism 16 into contact with the cornea of the eye 56. The compensating device 36 then establishes a substantially constant force between the eye 56 and the contact lens 54. If desired by the operator, the vacuum pump 62 can be activated to create a partial vacuum in the channels 58 to provide additional stability for the eye 56 during surgery. Any subsequent movement of the eye 56 will be opposed by the substantially constant force of the compensating device 36 and will cause movement of only the frame 30 and the components which are fixedly attached thereto.

As shown in FIG. 2 the frame 30 includes an opening 78 and an aperture 80 which establish an unobstructed path for laser beam 24 from the laser source 22, through both objective lens 40 and contact lens 54, and into the eye 56. In accordance with the structure disclosed for the preferred embodiment of the present invention, the eye 56 is maintained in a fixed relationship with the frame 30. Consequently, movement of objective lens 40 on frame 30 by activation of the objective lens actuator 50 results in the movement of the focal point of laser beam 24. This movement, when accomplished according to preprogrammed instructions from the computer 52, can be controlled to move the focal point of laser beam 24 along a prescribed path in the tissue of eye 56. Depending on the particular laser used, the energy level of the laser, its spot size, and the path which is established for movement of the focal point of the laser, ophthalmic surgery can be accomplished as desired by the operator while the mechanism 16 of the present invention stabilizes the eye 56 relative to the laser.

While the particular eye stabilizing mechanism for the present invention as herein shown and disclosed in detail is fully capable of obtaining the objects and providing the advantages herein before stated, it is to be understood that it is merely illustrative of the presently preferred embodiments of the invention and that no limitations are intended to the details of the construction or design herein shown other than as defined in the appended claims.

We claim:

1. A mechanism for stabilizing an eye with a contact lens and compensating for eye movement relative to the focal point of a laser beam during ophthalmic laser surgery which comprises:
a base;
means for supporting a contact lens, said supporting means being slidably mounted on said base;
means, attached to said base and connected to said supporting means, for generating a force against

said supporting means to hold said contact lens against the eye; and means mounted on said supporting means for moving said focal point along a preselected path relative to said contact lens to perform said surgery.

2. A mechanism as recited in claim 1 wherein said supporting means is a frame and said contact lens is slidably mounted on said frame for resting against the eye.

3. A mechanism as recited in claim 2 wherein said force generating means is a weight attached to said contact lens.

4. A mechanism as recited in claim 2 wherein said moving means is an objective lens slidably mounted on said frame for movement of said focal point, and said mechanism further comprises first means for locating said contact lens relative to said frame and second means for locating said objective lens relative to said frame.

5. A mechanism as recited in claim 1 wherein said supporting means is a frame and said contact lens is fixedly mounted on said frame.

6. A mechanism as recited in claim 5 wherein said force generating means connects said frame to said base for maintaining a substantially constant force between 25 said contact lens and the eye.

7. A mechanism as recited in claim 6 wherein said substantially constant force is in the approximate range of between zero and three hundred grams (0-300 gms).

8. A mechanism as recited in claim 6 wherein said frame is formed with an open channel having a first end and a second end, said second end of said channel being positioned against the eye when said contact lens is in contact with the eye, and wherein said mechanism further comprises:

a device selectively operable for creating a partial vacuum; and a tube connecting said vacuum creating device with said first end of said channel to establish a partial vacuum at said second end of said channel to hold 40 the eye against said contact lens.

9. A mechanism as recited in claim 1 wherein said moving means comprises:

a computer mounted on said base; an objective lens slidably mounted on said supporting 45 means; a computer controlled objective lens actuator fixedly mounted on said supporting means and electronically connected to said computer; and a link connecting said objective lens actuator with said objective lens for movement of said objective lens on said supporting means in accordance with preprogrammed instructions from said computer.

10. A support apparatus for holding a contact lens against the cornea of an eye during ophthalmic surgery involving movement of a focal point of a laser system which comprises:

a base; a frame for holding a contact lens, said frame being slidably mounted on said base;

a compensating device connecting said frame to said base for maintaining a substantially constant force between said contact lens and the cornea of the eye;

an objective lens slidably mounted on said frame; and means, mounted on said apparatus, for moving said objective lens relative to said contact lens to selectively move said focal point of said laser system.

11. An apparatus as recited in claim 10 wherein said moving means comprises:

a computer mounted on said base; a computer controlled objective lens actuator fixedly mounted on said frame and electronically connected to said computer; and a link connecting said objective lens actuator with said objective lens for movement of said objective lens on said frame in accordance with preprogrammed instructions from said computer.

12. An apparatus as recited in claim 10 wherein said substantially constant force is in the approximate range of between zero and three hundred grams (0-300 gms).

13. An apparatus as recited in claim 10 wherein said compensating device is a spring.

14. An apparatus as recited in claim 10 further comprising suction means for holding said contact lens in engagement with the cornea of the eye.

15. An apparatus as recited in claim 14 wherein said frame is formed with an open channel having a first end and a second end, said second end of said channel being positioned in contact with the cornea of the eye when said contact lens is in contact with the cornea of the eye, and wherein said suction means comprises:

a device selectively operable for creating a partial vacuum; and a tube connecting said vacuum creating device with said first end of said channel to establish a partial vacuum at said second end of said channel to hold the cornea of the eye against said contact lens.

16. A method for stabilizing the eye of a patient during ophthalmic laser surgery using an apparatus comprising a base, means slidably mounted on said base for supporting a contact lens, means mounted on said base and connected to said supporting means for generating a force against the supporting means to hold the contact lens against the eye, and means mounted on said supporting means for moving the focal point of a laser system along a preselected path relative to said contact lens; the method comprising the steps of:

positioning the contact lens against the eye; locating the objective lens of the laser system relative to the contact lens to establish a predetermined starting position for the focal point of the laser system; and maneuvering the focal point of the laser system along the preselected path to perform the ophthalmic surgery.

17. A method as recited in claim 16 wherein the supporting means is a frame and the frame is formed with an open channel having a first end and a second end, the second end of the channel being positioned against the eye when the contact lens is in contact with the eye, and wherein the apparatus further includes a device selectively operable for creating a partial vacuum; and the method further comprises the step of connecting a tube between the vacuum creating device and the first end of the channel to establish a partial vacuum at the second end of the channel to hold the eye against the contact lens.

18. A method as recited in claim 17 further comprising the step of generating a substantially constant force between the contact lens and the eye wherein the substantially constant force is in the approximate range of between zero and three hundred grams (0-300 gms).

19. A method as recited in claim 16 wherein the focal point is maneuvered along a preselected path for intrastromal photoablation.

20. A method as recited in claim 16 wherein the focal point is maneuvered along a preselected path for a phacemulsification procedure.

21. A mechanism for stabilizing eye movement relative to the focal point of a laser beam during ophthalmic 5 laser surgery which comprises:

a base;
a frame slidably mounted on said base and formed with an open channel having a first end and a second end, said second end of said channel being 10 positionable against the eye;
means, mounted on said base and connected to said frame, for generating a force against said frame to

hold said second end of said channel against the eye;
a device selectively operable for creating a partial vacuum;
a tube connecting said vacuum creating device with said first end of said channel to establish a partial vacuum at said second end of said channel to hold the eye against said frame; and
means mounted on said frame for moving said focal point along a preselected path relative to said frame to perform said surgery.

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United States Patent [19]

Raven et al.

[11] Patent Number: 4,994,058

[45] Date of Patent: * Feb. 19, 1991

[54] SURFACE SHAPING USING LASERS

[75] Inventors: **Antony L. Raven**, Hertfordshire; **John Marshall**, Hants, both of United Kingdom; **David F. Muller**, Boston, Mass.

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[*] Notice: The portion of the term of this patent subsequent to Aug. 15, 2006 has been disclaimed.

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[52] U.S. Cl. 606/5; 128/375; 128/897; 128/898; 219/121.060; 219/121.073; 219/121.085; 350/363

[58] Field of Search 128/303.1, 395, 347, 128/348, 897, 898; 606/5; 350/363; 219/121.60, 121.07, 121.68, 121.73, 121.85

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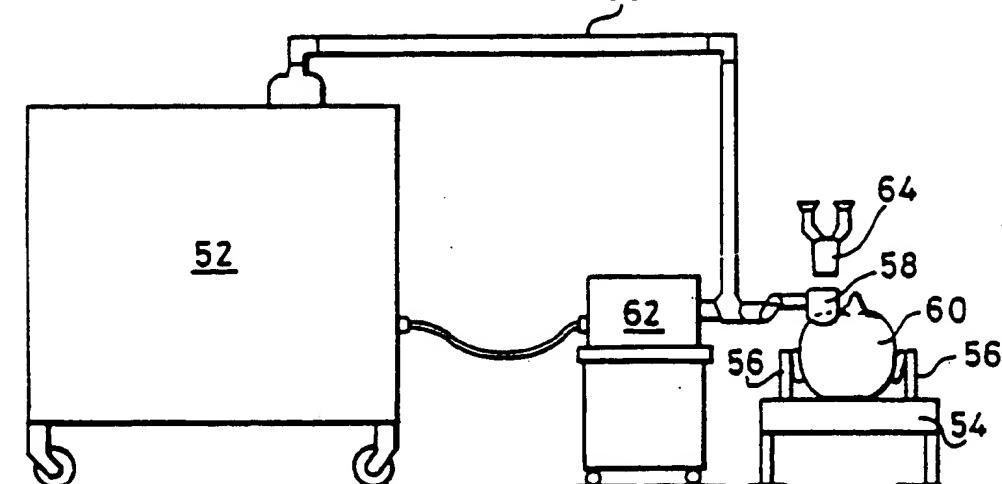
Attorney, Agent, or Firm—Thomas J. Engellenner

ABSTRACT

A laser system and masking apparatus for reprofiling surfaces, such as corneal surfaces. The system includes a laser and a mask disposed between the laser and the surface to be reprofiled, the mask providing a pre-defined profile of resistance to laser radiation, such that upon irradiation, part of the radiation is selectively absorbed and part is transmitted to the surface in accordance with the masked profile, to selectively erode the surface. The masking apparatus may consist of a mask to be affixed to the surface or may further include a support structure to support and position the mask above the surface. The resistance profile can be created by varying the thickness or the composition of the mask.

29 Claims, 4 Drawing Sheets

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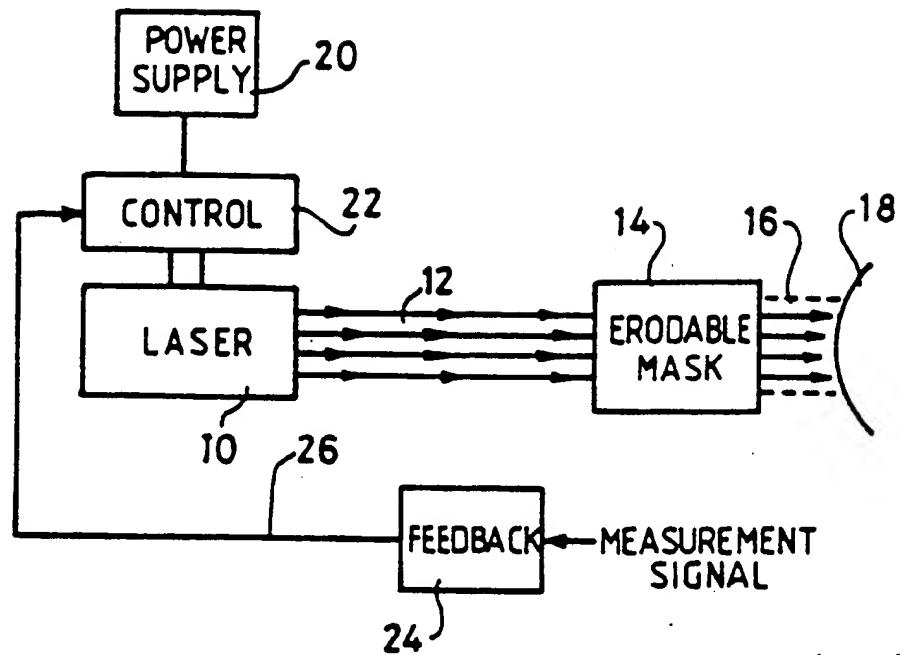


Fig. 1

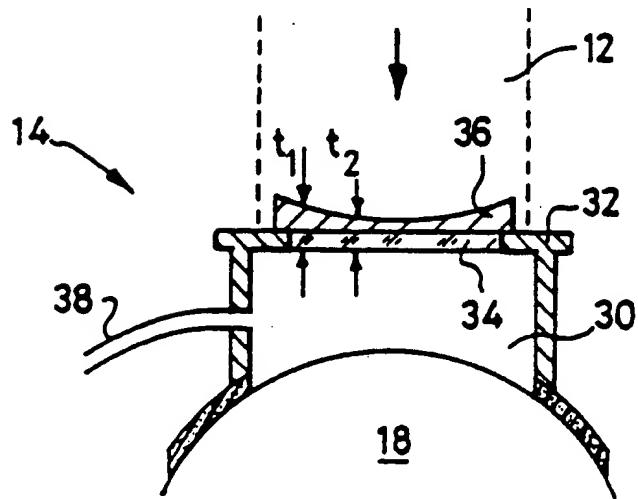


Fig. 2

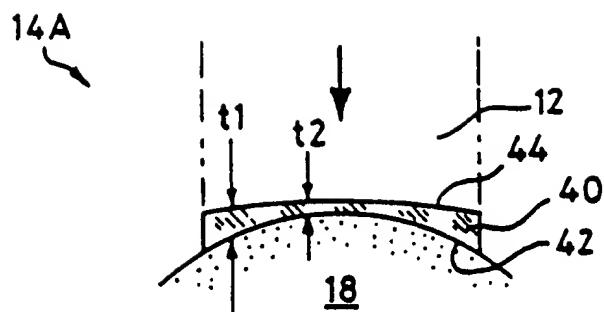


Fig. 3

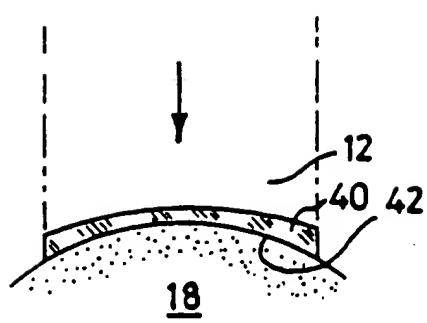


Fig. 4A

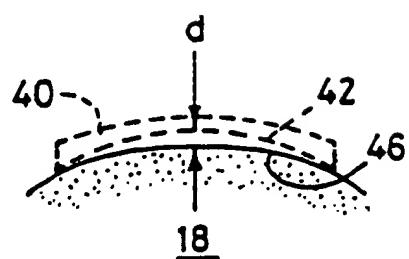


Fig. 4B

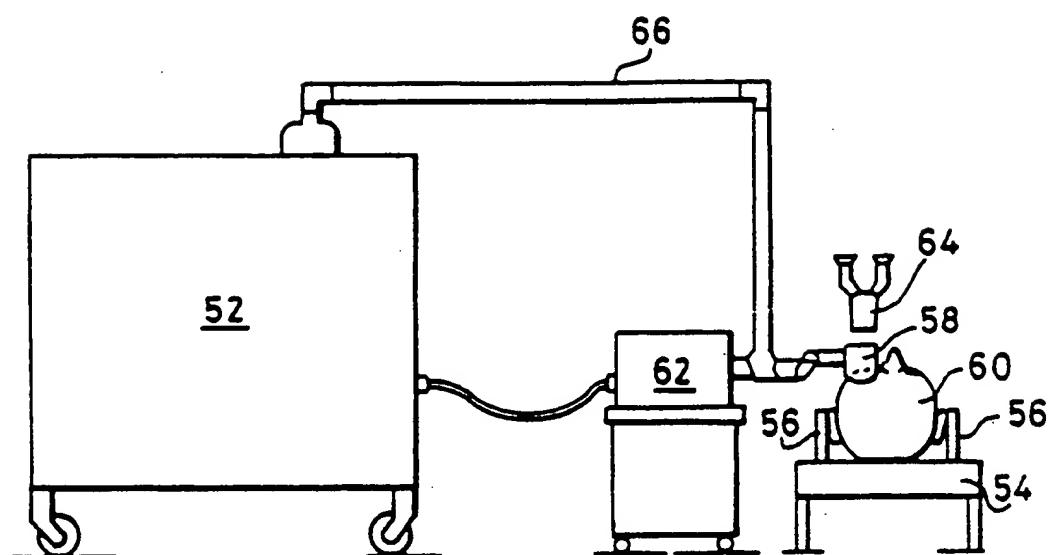


Fig 5

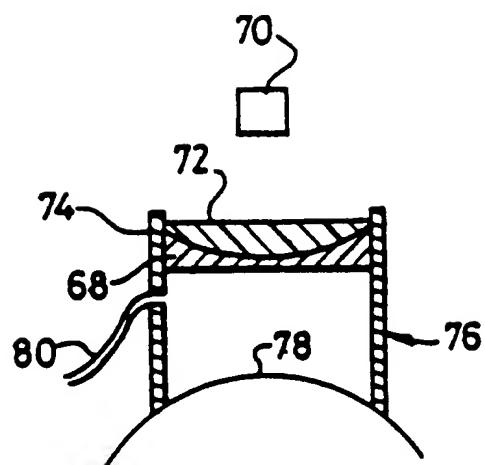


Fig. 6

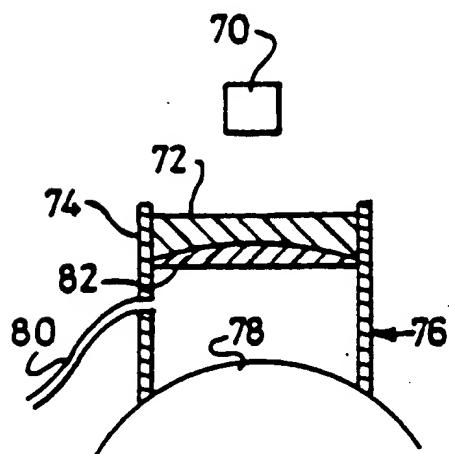


Fig. 7

SURFACE SHAPING USING LASERS

REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Ser. No. 19,200 filed Mar. 9, 1987 now U.S. Pat. No. 4,856,513.

DESCRIPTION

1. Field of the invention

This invention relates to apparatus and method employing lasers, especially pulsed lasers, for shaping surfaces, especially surfaces of organic material. In particular, the invention relates to apparatus and methods for shaping biological tissue, including the cornea of the eye.

BACKGROUND OF THE INVENTION

It is known to employ a laser source to erode surfaces of workpieces and the like. Such apparatus is in general relatively complex and demands highly skilled use. It is an object of the present invention to provide improved and simplified apparatus and method for eroding surfaces.

It is also an object of the present invention to provide an improvement whereby laser techniques can be applied to sensitive surfaces and in particular to objects in which it would be undesirable to affect underlying layers.

In the field of medicine, a known technique for the treatment of certain forms of myopia is surgically to remove a segment of the collagen sub-surface layer of the eye, to reshape the removed segment as by surgical grinding, and to restore the reshaped segment in the eye. The eye heals by reformation of the outer cellular layer over the reshaped collagen layer. Alternatively, a layer of the cornea is opened up as a flap, an artificial or donor lenticular implant is inserted under the flap, and the flap is sutured up again.

It is a further object of this invention to provide an improved and less traumatic method and apparatus for reshaping the cornea of the eye.

Various other surgical techniques for reprofiling of the corneal surface have also been proposed. One increasingly common technique is radial keratotomy, in which a set of radial incisions, i.e. resembling the spokes of a wheel, are made in the eye to remedy refractive errors such as myopia (nearsightedness). As the incisions heal, the curvature of the eye is flattened, thereby increasing the ocular focal distance. The operation is not particularly suitable for correction of hyperopia (farsightedness) and can pose problems if the surgical incisions are uneven or too deep.

The use of a laser beam as a surgical tool for cutting incisions, a so-called "laser scalpel", has been known for some time (see for example U.S. Pat. No. 3,769,963 to Goldman et al). In 1980, a study was made of the damage which might be inflicted on the corneal epithelium by exposure to the recently developed excimer laser (see Taboada et al, "Response of the Corneal Epithelium to ArF excimer laser pulses" *Health Physics* 1981, Volume 40, pp 677-683). At that period, surgical operations on the cornea were commonly carried out using diamond or steel knives or razor, and further such techniques were still being studied (see for example Binder et al, "Refractive Keratoplasty" *Arch. Ophthalmol.* May 1982, Vol. 100, p 802). The use of a physical cutting tool in corneal operations, and the insertion of an implant

under a flap, continue to be widely practised and techniques further developed up to the present day (see for example "Refractive Keratoplasty improves with Polysulfone, Pocket Incision" *Ophthalmology Times*, July 1, 1986).

It has been suggested in European Patent Application No. 01518699 of L'Esperance, to perform controlled ablative photodecomposition of one or more selected regions of a cornea using a scanning action on the cornea with a beam from an excimer laser. Because of the scanning action, it is necessary for L'Esperance to bring his laser beam to a small spot, typically a rounded-square dot of size 0.5 mm by 0.5 mm.

L'Esperance suggests that myopic and hyperopic conditions can be reduced by altering the curvature of the outer surface of the cornea by repeatedly scanning the cornea with an excimer laser beam having this standard small spot size by varying the field which is scanned during successive scans, so that some areas of the cornea are scanned more often than others. In this way, it is claimed that the surface can be eroded by different amounts depending on the number of times they are scanned by the spot. Additionally, he suggests that certain severe myopic and hyperopic conditions may be treated with a reduced removal of tissue by providing the outer surface of the cornea with a new shape having Fresnel-type steps between areas of the desired curvature.

In practice, complex apparatus is required to cause a laser beam to scan with the precision required if the eroded surface is to be smooth. Thus, if successive sweeps of a scan overlap, there will be excessive erosion in the overlap area, whereas if they fail to meet, a ridge will be left between the sweeps. The compression of the excimer laser beam to a small spot will increase the beam energy density, which will tend to exacerbate these problems. It is not clear that L'Esperance has found a suitable scanning system, since in one embodiment he attempts to control the laser beam by a magnetic field.

Additionally, the scanning method is inherently time-consuming even with highly refined techniques and apparatus, since the laser beam is only eroding a very small part of the total area to be treated at any given moment. Furthermore, such a scanning system can cause rippling effects on relatively soft materials such as corneal tissue.

It is therefore a further object of the present invention to provide a method and apparatus for eroding a surface using a laser which does not require scanning of the area of the surface to be eroded.

Another technique for corneal reshaping, described in British Patent Application No. 8604405 and herein incorporated by reference, involves the use of a laser photoablation apparatus in which the size of the area on the surface to which the pulses of laser energy are applied, is varied to control the reprofiling operation. In one preferred embodiment, a beam-shaping stop or window is moved axially along the beam to increase or decrease the region of cornea on which the laser radiation is incident. By progressively varying the size of the exposed region, a desired photoablation profile is established in the surface. For further details on this technique, see also, Marshall et al, "Photo-Ablative Reprofiling of the Cornea Using an Excimer Laser: Photorefractive Keratotomy", Vol. 1, *Lasers in Ophthalmology*, pp 21-48 (1986).

Although this technique for varying the size of the exposed region is a substantial improvement over physical shaping (i.e. scalpel) techniques and laser spot scanning protocols, a considerable number of optical elements and control systems still are required for precise operation, particularly on human corneal tissue. There exists a need for better and simpler procedures for shaping surfaces, particularly the surfaces of biological tissues, such as a corneal tissue.

THE INVENTION

According to one aspect of the present invention, there is provided, a laser apparatus for reprofiling a surface comprising, a laser means, control means for controlling the laser to project laser radiation towards the surface, and a masking means disposed between the laser means and the surface having a predefined profile of resistance to the laser radiation, so that upon irradiation of the masking means, a portion of the laser radiation is selectively absorbed and another portion is transmitted to the surface, in accordance with the mask profile, to selectively erode the surface.

The masking means may be formed from material which is ablated by absorption of the laser radiation so that the masking means is progressively destroyed during the surface reprofiling.

Alternatively the masking means may be formed from material which has differing transmission characteristics over the masked area but which is not substantially ablated or otherwise eroded during the surface reprofiling.

The masking means may comprise a lens-like device which is supported by a rigid structure which is affixed to the surface, (for example to the sclera of an eye where the apparatus is to be used in conjunction with corneal surgery), the lens being connected to the support structure and disposed above the surface either in contact with the surface or a small distance thereabove. The lens can be directly integrated with the support structure or, preferably, the support structure may include a transparent stage to support and position the lens.

In another embodiment, the masking means may comprise a contact-type lens device which is disposed upon, and directly affixed to, the surface (e.g. the cornea of an eye in the case of corneal surgery). Typically the contact-type lens is constructed so as to have a first surface contoured to fix to the surface to be eroded and a second surface contoured to provide the desired surface contour following erosion by exposure to laser radiation.

In a further embodiment the masking means may comprise a tray or well of optically transparent material in which a quantity of a selected masking material in the form of a liquid or gel or gas or vapour or volatile material can be contained. The base of the tray or well may be curved so that the underside of the masking material contained therein is either convexly or concavely shaped to define a "lens". By choice of material so the absorption of the laser light by the masking material will cause selective erosion of the surface below the tray or well. The latter may be supported on or above the surface and may be in contact with the surface if desired.

Whichever is selected, a masking lens of the present invention provides a predefined profile or resistance to erosion by laser radiation. Such profiles can be provided by varying the thickness or composition of the

lens material. When the thickness of the lens is varied, and dependent on the nature of the erosion of the object which is required, the lens may be convexo-concave, plano-convex, plano-concave, convexo-convex or concavo-concave, and it may also be aspheric or toroidal at least on one surface. In special cases the surface shape may be irregular, as might be required in the case of surgery on a cornea to remove an ulcer.

Conveniently the lens material has similar ablation characteristics to the surface material. Various polymeric materials can be employed including, for example, polymethylmethacrylate, polymethylstyrene and mixtures thereof. For corneal reprofiling, the ablation characteristics of the masking material can range from about 10^3 to about 10^6 cm^{-1} . Preferably, the masking material has an absorption characteristic of micron or submicron etch depths per pulse similar to those of the cornea when it is exposed to pulsed UV excimer laser radiation.

According to another aspect of the invention, there is provided a method of reprofiling a surface comprising

(a) locating a laser means relative to an optical axis of a surface, the laser means being operable to deliver laser radiation to the surface; and

(b) disposing a masking means between the laser means and the surface, the masking means having a predefined profile of resistance to the laser radiation, and

(c) irradiating a portion of the radiation is selectively absorbed and another portion is transmitted to the surface in accordance with the mask profile, to selectively erode the surface.

The method may include varying the thickness of the masking means or varying the composition of the masking means, to provide the desired resistance profile.

Typically, the laser is set to operate so that a single pulse erodes a depth in the range 0.1 to 1 micrometer of surface material.

The method may be applied to any ablatable surface including biological tissue such as a ligament or a cartilage in a bone.

The method of the present invention is particularly well suited for controlled reprofiling of the cornea, particularly the collagen sub-layer thereof which lies immediately below the uniform, extremely thin, epithelial layer of the cornea, which is very rapidly ablated on exposure to the laser light. The extremely thin surface layer heals and eventually reforms following the reshaping operation. In surgical applications, the laser light is of a wavelength obtainable from a UV Argon Fluoride laser, typically about 193 nanometers, which does not penetrate through the cornea. A minimum laser irradiance level is essential for ablation, but it is preferred not greatly to exceed this minimum threshold.

The pulse repetition rate for the laser may be chosen to meet the needs of each particular application. Normally, the rate will be between 1 and 500 pulses per second, preferably between 1 and 100 pulses per second.

Suitable irradiation intensities vary depending on the wavelength of the laser, and the nature of the irradiated object. For any given wavelength of laser energy applied to any given material, there will typically be a threshold value of the energy density below which significant erosion does not occur. Above the threshold density, there will be a range of energy density over which increasing energy densities give increasing depths of erosion, until a saturation value is reached.

For increases in energy density above the saturation value, no significant increase in erosion occurs.

The threshold value and the saturation value will vary from wavelength to wavelength of laser energy and from material to material of the surface to be eroded. However, for any particular laser and any particular material, the values can be found readily by experiment. For example, in the case of eroding a mask and the underlying corneal stroma (collagen sub-layer) by energy of wavelength 193 nm (the wavelength obtained from an ArF excimer laser), the threshold value is about 50 mJ per cm^2 per pulse, and the saturation value is about 250 mJ per cm^2 per pulse. There appears to be little benefit in exceeding the saturation value by more than a small factor, and suitable energy densities at the corneal surface are 50 mJ per cm^2 to 1 J per cm^2 per pulse for a wavelength of 193 nm.

The threshold value can vary very rapidly with wavelength, and at 157 nm, which is the wavelength obtained from an F₂ laser, the threshold is about 5 mJ per cm^2 per pulse. At this wavelength, suitable energy densities at the corneal surface are 5 mJ per cm^2 to one J per cm^2 per pulse.

Most preferably, the laser system is used to provide an energy density at the surface to be eroded of slightly less than the saturation value. Thus, when eroding the cornea with a wavelength of 193 nm (under which conditions the saturation value is 250 mJ per cm^2 per pulse), it is preferable to provide to the erodable mask and cornea pulses of an energy density of 100 to 150 mJ per cm^2 per pulse. Typically, a single pulse will erode a depth in the range 0.1 to 1 micrometer of collagen from the cornea.

The invention also lies in a system for reprofiling a surface using laser radiation in which masking means is disposed between the source of laser radiation and the surface for providing a predefined profile of resistance to the said laser radiation, such that upon irradiation of the masking means a portion of the laser radiation is selectively absorbed and another portion is transmitted to the surface, in accordance with the mask profile, to selectively erode the surface.

The surface which undergoes erosion may be biological tissue, particularly corneal tissue, and may include means to immobilise the surface.

The masking means may include a rigid support structure affixed to the surface with a masking lens connected to the support structure and disposed above the surface. The support structure further may include a transparent stage with the masking lens affixed to the stage. The masking lens may vary in thickness, or may vary in composition to provide the predefined profile of resistance.

The lens may be formed from polymethylmethacrylate, polymethylstyrene, or mixtures thereof.

The masking means may include a masking lens disposed upon, and directly affixed to, the cornea, which as above described may vary in thickness or in composition, to provide the predefined profile of erosion resistance. As before the lens may be formed from polymethylmethacrylate, polymethylstyrene, or mixtures thereof.

The laser source may be a pulsed excimer laser, typically an Argon-Fluoride laser operating at a wavelength of about 913 nanometers.

The invention also lies in masking apparatus for use in laser reprofiling of corneal tissue comprising a rigid support structure adapted for fixation upon a cornea,

and a mask connected to the support structure and disposed above the cornea, the mask having a predefined profile of resistance to the laser radiation, whereby upon irradiation of the mask, a portion of the laser radiation is selectively absorbed and another portion is transmitted to the cornea in accordance with the mask profile to selectively erode the tissue.

The support may include a transparent stage adapted to receive the mask.

The mask may comprise a lens which varies in thickness or composition, to provide the profile.

The mask may be formed from polymethylmethacrylate, polymethylstyrene, or mixtures thereof.

The invention also lies in masking apparatus for use in laser reprofiling of corneal tissue comprising a masking lens adapted for direct fixation upon a cornea, the lens having a predefined profile of resistance to erosion by laser radiation, whereby upon irradiation of the lens, a portion of the laser radiation is selectively absorbed and another portion is transmitted to the cornea in accordance with the lens profile to selectively erode the tissue.

The lens may have a diameter in the range of about 3 to 12 millimeters and a maximum thickness of about 2 millimeters or less, and may vary in thickness, or in composition to provide the profile.

The masking means may be secured to the cornea by a suction means and a vacuum pump may be provided to reduce the pressure within the suction means, to fix the suction means in place on the cornea. As before the lens may be formed from polymethylmethacrylate, polymethylstyrene, or mixtures thereof, or the lens may be formed by a mass of material contained in a well or dish, above the cornea, which is optically transparent to the laser radiation.

The well or dish may include a transparent lid or cover, and the well or dish may be a liquid or gel, or gas or a vapour.

The apparatus may be formed at least in part from a material which is ablated or eroded by the laser radiation, said resistance being a measure of the resistance to ablation or erosion by the laser radiation.

The rate of ablation or erosion for the lens material may be substantially the same on the rate of ablation or erosion of the corneal surface.

The invention will next be described in connection with certain illustrated embodiments; however, it should be clear that those skilled in the art can make various modifications, additions and subtractions without departing from the spirit or scope of the invention. For example, the invention can be used in connection with corneal transplants where a donor insert is stitched into the patient's eye. Quite often, accidental overtightening of the stitches introduces refractive errors in the cornea following the operation. At present, the transplant operation must be repeated or relaxing incisions must be made in the cornea. The present invention can provide an improved and less traumatic method for remediating such refractive errors.

Additionally, the present invention can be applied to the remedy of stigmatisms, corneal ulcers and keratomic growths which affect vision. In such instance, specific masks can be designed and constructed to selectively remove the corneal tissue which interfere with normal refraction.

Moreover, the teaching of the present invention can be applied to other biological tissues requiring reprofil-

ing including, for example, ligaments, cartilage, and bone.

DESCRIPTION OF THE DRAWINGS

The invention will now be described by way of example with reference to the accompanying drawings, in which:

FIG. 1 is a diagrammatic illustration of an apparatus for practicing a method of reprofiling the surface of an object, in accordance with the invention;

FIG. 2 is a more detailed illustration of an erodable mask suitable for use in the apparatus of FIG. 1;

FIG. 3 is an illustration of alternative embodiment of an erodable mask suitable for use in the apparatus of FIG. 1;

FIG. 4A illustrates diagrammatically the beginning of a reprofiling operation to reduce the curvature of an object in accordance with the present invention;

FIG. 4B illustrates diagrammatically the completion of the reprofiling operation of FIG. 4A;

FIG. 5 shows a laser apparatus for measurement and reprofiling;

FIG. 6 illustrates a modified version of the apparatus as shown in FIG. 2, capable of retaining a liquid or gel as a convex lens-like mask, and

FIG. 7 illustrates a modification to the arrangement of FIG. 6 in which a concave lens-like mask of liquid or gel can be formed.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

In FIG. 1, a laser 10 provides a radiation output 12 to an erodable mask 14 which provides a predefined profile of resistance to the radiation. A portion of the laser radiation 16 is selectively transmitted in accordance with the profile of mask 14 and irradiates the surface 18 of the object which is to be reprofiled and which as shown may comprise the cornea of an eye.

The laser is powered by a power supply unit 20 and control circuit 22 which can be adjustable to cause the laser to produce pulses of light at a specific frequency and intensity. To further control the laser, a feedback device 24 can be provided which receives information from optical or other inspection of the mask 14 and/or surface 18 while it is exposed to irradiation by the laser 10. A feedback path 26 communicates with the control circuit 22 for controlling the laser 10.

In FIG. 2, one embodiment of the erodable mask 14 of FIG. 1 is shown in more detail. As illustrated, the erodable mask 14 includes a suction cup 30 which provides a support structure having rigid vertical walls and a horizontal surface 32. At least a portion of the horizontal surface 32 is formed by a transparent stage 34. Preferably, the remainder of surface 32 is opaque to laser radiation. Disposed upon the transparent stage 34 is masking lens 36.

The entire structure can be placed upon the surface of the object, i.e. the sclera of an eye, leaving the corneal surface 18 unobstructed. A flexible tube 38 supplies vacuum suction to the cup, so as to clamp it to the eye with a force sufficient to hold it in place but not distort the shape of the cornea.

The erodable mask 14 can be rigidly connected to the laser or otherwise optically aligned therewith such that pulsed radiation from the laser can be selectively transmitted through the mask to produce the desired erosion of the surface.

In FIG. 3, an alternative embodiment of the invention is shown wherein an erodable mask 14A is formed by a contact-type lens 40 fitted to the object, i.e. the surface of an eye 18 over the area to be treated. As in FIG. 2, the lens 40 is uniformly irradiated with a pulsed beam of light 12 obtained from a laser radiation source.

The lens, as fitted, has a lower surface 42 of a shape matching the existing contour of the object and an upper surface 44 matching the shape of the object de-sired after reprofiling.

Both lens 36 of FIG. 2 and lens 40 of FIG. 3 illustrate how the erodable mask can vary in thickness to provide a predefined profile of resistance. The selected lens material is a material which is erodable by laser radiation and preferably has ablation characteristics substantially identical to the object material. Most preferably, the maximum thickness t_1 of the lens exceeds the minimum thickness t_2 by an amount approximately equal to the maximum depth d of erosion required to complete the reprofiling of the surface.

For example, the erodable masks of the present invention can be formed from plastics material such as poly(methylpethacrylate) (PMMA) or poly(methyl styrene) (PS). These polymers are both bio-compatible and can be efficiently eroded by laser radiation, i.e. by a pulsed ArF excimer laser (193 nm). These polymers are mutually soluble in each other, and by changing the concentration of PS in PMMA, absorption coefficients can be varied from about 10^3 to about 10^6 cm^{-1} . Other organic polymers exhibiting suitable ablation characteristics can also be employed in the manufacture of erodable masks. For use in corneal surgery the polymeric material preferably has an absorption characteristic of micron or submicron etch depth per pulse, similar to the absorption characteristics of the cornea. For further details on organic polymers suitable for construction of masks, see Cole et al, "Dependence of Photoetching Rates of Polymers at 193 nm on Optical Absorption Coefficients", Vol. 48 *Applied Physics Letters*, pp 76-77 (1986), herein incorporated by reference.

Various techniques can be employed to manufacture the lenses used in the present invention from PMMA or PS. These techniques included injection moulding, casting, machining and spin casting. Manufacture by laser machining can also be employed. In one typical technique, a solution of PMMA or PS is prepared in toluene and spin cast in a suitably-shaped cup to obtain a smooth, uniform lens having a pre-defined profile thickness. Depending upon the concentration of PS in PMMA, a suitable absorption coefficient is obtained. The films can then be removed from the spin cup and vacuumed baked to residual solvent.

Alternatively, the erodable mask can be made of a material having a variable composition such that predefined regions of the mask selectively absorb greater amounts of laser radiation even though the entire mask has a uniform thickness. Again, materials such as PMMA and PS can be employed in varying concentrations in the erodable mask to achieve the variable composition of the mask.

Figs. 4A and 4B illustrate the principle involved in eroding a surface to effect reprofiling thereof in accordance with the present invention. Although FIGS. 4A and 4B illustrate this principle in connection with a contact-type masking lens disposed directly upon the surface, it should be clear that the same principles are applied when a support structure is affixed to the surface and a masking means is disposed upon the support

structure. Where the "lens" is convex and is to be eroded simultaneously a the surface below, it is a prerequisite that either the lens is of the so-called "contact" type, or it is supported on a transparent platform or window.

In FIGS. 4A and 4B, the reference 18 denotes the object such as the cornea of an eye to be reprofiled and, in FIG. 4A, reference 40 denotes a contact-type masking lens fitted to the eye over the area thereof to be treated. Also as indicated in FIG. 4A, the lens 40 is uniformly irradiated with a beam of radiation 12 obtained from a pulsed UV laser source.

The lens, as fitted, has a lower surface 42 of a shape matching the existing contour of the object in an upper surface which provides the desired degree of reprofiling. During the radiation, the lens 40 is gradually ablated, and an increasing area of the object becomes exposed to erosion. As indicated in FIG. 4B at the moment when the lens has been wholly ablated, the surface of the object has been eroded as indicated at 46, to the extent necessary to complete reprofiling over the area to which the lens has been fitted. As shown in FIG. 4B, the maximum thickness of the lens 40 exceed the minimum thickness by an amount equal to the maximum depth (d) of the object erosion desired.

As hereinbefore explained, the present invention is especially suited to the treatment of the cornea of an eye and provides a less dramatic means of effecting reprofiling of the cornea, for example, as a remedy for certain forms of refractive errors. FIGS. 4A and 4B illustrate the methods of the present invention in connection with the treatment of myopia (nearsightedness). Similar lenses of appropriate shape can, of course, be employed to remedy other forms of refractive errors, such as hyperopia and astigmatism.

FIG. 5 illustrates an apparatus for reprofiling the cornea of a human eye in accordance with the invention. A laser and associated control circuitry is contained in a housing 52. The beam-forming optics, for providing a beam of desired shape and size, can also be contained within the housing 52 together with the laser power supply control circuits. An optical wave guide 66, which can be flexible or rigid and includes suitable mirrors, prisms and lenses, is provided to transmit the laser beam output from the housing 52 to the patient 60. The patient 60 is lying face-upwards on an operating table 54. The operating table 54 will support the patient's head against vertical movement. If desired, side supports 56 may also be provided to restrain sideways movement of the patient's head.

The erodable mask of the present invention is disposed within an eyepiece 50A adapted to fit over the patient's eye. The eyepiece 58 includes suction means for providing suction to clamp the eyepiece over the patient's eye. The eyepiece can include a cup of resiliently deformed flexible material such as rubber or plastics material which when placed over the eyeball will clamp thereto upon being evacuated. Also disposed within the eyepiece are suitable optical elements for transmitting the laser radiation to the surface of the eye, and the erodable mask similar in structure to either the erodable mask shown in FIG. 2 or FIG. 3 above. The erodable mask is manufactured as described above based on measurements of the patient's eye and has a profile which will impart the desired refraction correction upon erosion.

During the operation, the eye can be observed using a surgical microscope 64 which is supported above the

patient by any convenient means. The surgical microscope 64 may be connected to the eyepiece 58, but will more normally be separated therefrom and supported by an arm (not shown) from the ceiling or by a cantilever (not shown).

A measuring device 62 can also be employed in conjunction with the present apparatus to measure the changes in the curvature of the cornea following operation. Such a measuring device 62 can also be employed to monitor the degree of erosion of the mask during treatment. The measuring device can take the form of a commercially-available keratometer or other suitable device and as shown in FIG. 5, can be connected directly to the laser optical path or may be movable when needed to occupy the position shown for the surgical microscope 64, the operator moving the measuring device 62 or the microscope 64 into position as required.

The measuring device 62 can further provide the feedback control, as shown in FIG. 1, whereby information from optical or other inspection of the surface which is being exposed to laser erosion is used to control the actual duration and amplitude of the pulses supplied by the laser and may be tuned so as to produce just the desired degree of erosion of the surface by each pulse.

A modification is shown in FIGS. 6 and 7 which possesses two advantages:

(1) materials which are not rigid and self supporting or which heat up sufficiently during exposure to the laser pulses as to become liquid or gel-like, may be employed,

(2) the need for accurately manufacturing curved elements which are then to be destroyed, can be avoided, since the curved shape is provided by the base of the tray (or well), which being transparent to the wavelengths involved, does not absorb radiation and is therefore not destroyed.

This second feature is of particular value in apparatus and methods which are to be applied to the shaping of surfaces to a uniform standard. It is of less importance when each process is a "one-time only" procedure requiring a particular shaping to be achieved - as is usually the case in corneal surgery.

To this end FIG. 6 shows a device in which a dished member 68 of a material which is transparent to radiation from a laser 70, provides a transparent support for a liquid 72. The liquid is contained by a peripheral wall 74 which is a continuation of a support ring 76 which itself rests on and is clamped to the surface 78 to be ablated by the laser radiation. A vacuum pump (not shown) is connected to the ring 76 via a tube 80, and operated to evacuate the ring, and clamp it to the surface.

The choice of the material 72 is governed by the erosion characteristics of the surface 78. Ideally the material 72 should be "eroded" at the same rate as the material forming the surface 78 so that the final shape of the surface 78 will be substantially the same as that of the surface of the dished member 68. As shown this is concavely profiled.

If a convex profile is required in the surface 78, a convexly profiled base member 82 is employed in place of the element 68 of FIG. 6. Such an element is shown in FIG. 7. In all other respects FIG. 7 is the same as FIG. 6 and the same reference numerals have been used throughout.

The material 72 may be solid, liquid or a gel. If thermoplastic or thermosetting the material may for example introduced into the tray (74, 68) or (74, 82) and heated to allow it to flow and conform to the shape of the base 68, 82.

By fitting a transparent lid, to the rim of the wall 74, a gas or vapour or volatile material may be employed as the material 72.

We claim:

1. An erodable mask for reprofiling a surface using laser radiation, the mask comprising a material erodable by laser radiation and positionable between a source of laser radiation and the surface, the mask providing a predefined profile of resistance to the said laser radiation, such that upon irradiation of the mask a portion of the laser radiation is selectively absorbed by the mask and another portion is transmitted to the surface in accordance with the mask profile, to selectively erode the surface.

2. The apparatus of claim 1 wherein the apparatus further comprises means for immobilizing the surface.

3. The mask of claim 1, wherein the mask material comprises a material selected from the group consisting of polymethylmethacrylate, polymethylstyrene and mixtures thereof.

4. The apparatus of claim 1, wherein the mask is disposed upon, and directly affixed to, the surface.

5. The mask of claim 4, wherein the mask varies in thickness to provide the predefined profile of resistance.

6. The mask of claim 4, wherein the mask varies in composition to provide the predefined profile of resistance.

7. A masking apparatus for use in laser reprofiling of corneal tissue comprising an erodable mask being erodable by radiation from a laser and capable of direct fixation upon a cornea, the mask having a predefined profile of resistance to the laser radiation, whereby upon irradiation of the mask, a portion of the laser radiation is selectively absorbed by the mask and another portion is transmitted to the cornea in accordance with the mask profile to selectively erode the tissue.

8. The apparatus of claim 7, wherein the mask varies in thickness to provide the said profile.

9. The apparatus of claim 7, wherein the mask varies in composition to provide the said profile.

10. The apparatus of claim 7, wherein the mask is fixable to the corneal surface by a suction means.

11. The apparatus as claimed in claim 7, wherein the mask is formed at least in part from a material which is ablated or eroded by the laser radiation, the said resistance being a measure of the resistance to ablation or erosion by the laser radiation.

12. The apparatus of claim 7, wherein the mask has a diameter in the range of about 3 to 12 millimeters and a maximum thickness of about 2 millimeters or less.

13. The apparatus of claim 12, wherein the mask is formed from polymethylmethacrylate, polymethylstyrene, or mixtures thereof.

14. Laser apparatus for reprofiling a surface comprising a laser means, control means for controlling the laser means to project laser radiation towards the surface, and an erodable masking means adapted to be disposed between the laser means and the surface, said masking means being erodable by the radiation from the laser means and having a predefined profile of resistance to the laser radiation, so that upon irradiation of the masking means, a portion of the laser radiation is selectively absorbed by the masking means and another

portion is transmitted to the surface in accordance with the mask profile to selectively erode the surface.

15. Laser apparatus as claimed in claim 15, in which the masking means is formed from material which is ablated by absorption of the laser radiation so that the masking means is progressively destroyed during the surface reprofiling.

16. Laser apparatus as claimed in claim 14, in which the masking means comprises a tray or well of optically transparent material in which a quantity of a selected masking material can be contained.

17. Laser apparatus as claimed in claim 14, in which the material forming the masking means is selected to have similar ablation characteristics to the surface material.

18. Laser apparatus as claimed in claim 14, in which the masking means is formed from polymethylmethacrylate or polymethylstyrene or mixtures thereof.

19. Laser apparatus as claimed in claim 14, in which the masking means comprises a mask which is adapted to be disposed upon, and directly affixed to, the surface.

20. Laser apparatus as claimed in claim 19, in which the mask is constructed so as to have a first surface contoured to conform to the surface to be eroded and a second surface contoured to provide the desired surface contour following erosion by exposure to laser radiation.

21. The apparatus of claim 14, wherein the laser means is a pulsed excimer laser.

22. The apparatus of claim 21 wherein the excimer laser is an Argon-Fluoride laser operating at a wavelength of about 193 nanometers.

23. A method of reprofiling a surface comprising: locating a laser means relative to a surface, the laser means being operable to deliver laser radiation to the surface; and disposing an erodable masking means between the laser means and the surface, the masking means being erodable by radiation from the laser means and having a predefined profile of resistance to the laser radiation, and

irradiating the masking means, whereby a portion of the radiation is selectively absorbed by the masking means and another portion is transmitted to the surface, in accordance with the mask profile, to selectively erode the surface.

24. A method as claimed in claim 23 wherein the step of locating a laser means relative to a surface further comprises locating the laser means relative to a cornea of the eye.

25. A method as claimed in claim 23 wherein the step of locating a laser means relative to a surface further comprises locating the laser means relative to a biological tissue such as a ligament or a cartilage in a bone.

26. A method as claimed in claim 23, wherein the method further includes varying the thickness of the masking means to provide the profile of resistance.

27. A method as claimed in claim 23, wherein the method further includes varying the composition of the masking means to provide the profile of resistance.

28. A method as claimed in claim 23, wherein the step of irradiating the masking means further includes irradiating the masking means with a pulsed laser means.

29. A method as claimed in claim 28, wherein the step of irradiating the masking means further includes irradiating the masking means with a single pulse which is set to erode a depth in the range 0.1 to 1 micrometer of surface material.

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